# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.

10/544,151

Confirmation No. 6429

Applicant

Francis X. Smith

Filed

August 1, 2005

Art Unit: 1612

Title

OPHTHALMIC AND CONTACT LENS

SOLUTIONS CONTAINING SIMPLE SACCHARIDES AS

PRESERVATIVE ENHANCERS

Examiner

Zohreh A. Fay

Docket No. :

3009108 US01

Customer No.:

44,331

Mail Stop: AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

# PRE-APPEAL BRIEF REQUEST FOR REVIEW

Appellant hereby requests an appeal conference for review of claims 1-4 and 6-9 for the above referenced application.

A timely Notice of Appeal, in compliance with 37 CFR 41.31, is filed with this Pre-Appeal Brief Request for Review.

# **Status Of The Claims:**

Claims 1-4 and 6-9 are pending in the application.

Claims 1-4 and 6-9 are rejected.

Claims 1-4 and 6-9 are hereby appealed.

#### **Status Of Amendments:**

A Response After Final was filed on March 12, 2009, subsequent to the Final Rejection. An Advisory Action dated April 10, 2009 was then received indicating that the claims are not in condition for allowance.

ROCHDOCS\547013\1 - 1 -

#### Remarks

#### **Response to Advisory Action:**

In the Advisory Action dated April 10, 2009, it is stated that Asgharian teaches a single part solution that has all the elements of the claimed composition. However, this indication is erroneous.

Asgharian does not disclose a single-part solution that contains 0.001 to 10 weight percent of a claimed preservative enhancer, at least 0.0001 weight percent polyhexamethylene biguanide and less than 0.2 weight percent chloride. The only solution disclosed containing at least 0.0001 weight percent polyhexamethylene biguanide is solution B. (col. 15, lines 12-24). However, solution B has a chloride concentration in excess of 0.2 weight percent. Furthermore, solution B does not disclose containing a claimed preservative enhancer. Therefore, it is respectfully urged that Asgharian does not teach this limitation and that this rejection be reversed.

## Rejection under 35 U.S.C. § 103(a) over Asgharian et al.:

The Office Action dated January 13, 2009 rejects claims 1-4 and 6-9 under 35 U.S.C. § 103(a) as being unpatentable over Asgharian et al (U.S. 6,139,646) indicating that Asgharian et al. teaches the use of a simple saccharide in a composition that contains PHMB. However, the Office Action dated January 13, 2009 fails to set forth a *prima facia* case of obviousness.

#### Asgharian fails to teach all of the claimed limitations:

Asgharian relates to improving the stability of liquid enzyme solutions containing both covalently modified trypsin and water using organic stabilizers. The stabilizers compete with water in the hydrogen bonding of the liquid enzyme solution to reduce the water-hydrogen bonding necessary for enzyme activity.

The instant claims relate to an effective single-part aqueous solution with a specific combination and concentrations of a preservative enhancer, polyhexamethylene biguanide and chloride. The inventive solution is effectively preserved while reducing the amount of preservatives deposited on contact lenses.

ROCHDOCS\547013\1 - 2 -

Asgharian teaches a two-part solution where trypsin is an active ingredient in a first part that is combined with the second part. The second part contains sorbitol with a concentration of 1.2 weight/volume. There is no indication that the second solution would be effective as a contact lens solution by itself. Indeed, Asgharian teaches that the second part, the solution, need be combined with the first component containing trypsin to be effective. By contrast, the present claims recite a single-part solution that is effective as a contact lens solution without the need to combine with a second part. The omission of an element and the retention of its function is an indicia of non-obviousness. *In re Edge*, 359 F.2d 896, (CCPA 1966). As Asgharian does not teach a single-part solution, it respectfully urged that Asgharian fails to teach or suggest all of the claimed limitations and that this rejection be reversed.

### The January 13, 2009 Office Action fails to address all of the claimed limitations:

The Amendment filed October 29, 2008 amended the claims to recite an aqueous solution that is effective as a single-part-solution. As discussed above, Asgharian teaches a multi-part solution that must be combined to be effective. As the Office Action dated January 13, 2009 fails to address the claimed limitation of a single-part solution, it is requested that this rejection be reversed.

#### Conclusion:

For the above reasons, Appellant respectfully requests reversal of the rejection and an indication of allowance for claims 1-4 and 6-9.

In the event that Applicant has overlooked the need for an extension of time, additional extension of time, payment of fee, or additional payment of fee, Applicant hereby conditionally petitions therefore and authorizes that any changes be made to Deposit Account No.: 50-3010.

ROCHDOCS\547013\1 - 3 -

Respectfully submitted,

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